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Claim rejections – 35 U.S.C. § 112

Claim 14 has been rejected under 35 USC §112, second paragraph, as being indefinite. The Examiner is of the opinion that the claim is drawn to a method wherein the oligonucleotide is a randomer oligonucleotide, which does not particularly point out or distinctly claim the invention since a single oligonucleotide can not be a randomer. In order to accelerate prosecution of the present application, the Applicants wish to point out that claim 14 has been amended in the Response filed September 5, 2008 which is considered as a submission as mentioned in the PTO/SB/30EFS form submitted concurrently, to no longer define that the oligonucleotide is a randomer oligonucleotide in the response filed September 5, 2008. Reconsideration and withdrawal of the Examiner's rejection are earnestly solicited.

Claim rejections - 35 U.S.C. § 102(b)

Claims 1, 2, 14, 17, 18, 21, 23, 27, 28, and 30-32 have been rejected under 35 U.S.C. 102(b) for allegedly being anticipated by Krieg et al. The Examiner is mentioning that the reference of Krieg et al. teaches an immunostimulatory composition comprising nucleic acid molecules in the range of 8 to 40 base pairs in size comprising phosphorothioate stabilized oligonucleotides.

The Examiner stated in the Advisory Action issued on November 14, 2008, that in the previous response submitted September 5, 2008, the limitation included in amended claims 1, 2 and 14 requires an additional search in the art and thus, the proposed amendment was not entered. In this regard, the Applicants believe that the amendment to claims 1, 2 and 14, further restricting (thus narrowing the scope of the claims) that the oligonucleotides recited in the claims, does not represent new subject matter. Claim 1 has been amended in order to specifically encompass oligonucleotides having a sequence not comprising an immune system interacting CpG portion. In addition claim 2 has been amended to further define that the oligonucleotides comprises only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG which represent a subset or a selection of possible sequences disclosed in paragraph [0068] of the published application. Claim 14 has been amended in order to further define that the sequence of the encompassed oligonucleotides comprises only C, A or T nucleotides, which represents a selection of nucleotides disclosed in the published specifications at paragraph [0068]. All of these amendments only restricted further the scope of the claims without departing from the

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original broad scope of the claims that were searched. It is submitted that the original search is still applicable and thus no additional searches are believed to be required, as the original one encompassed the subject matter now claimed.

Claims 1, 2 and 14 were amended in the Response filed September 5, 2008 which is considered as a submission as mentioned in the PTO/SB/30EFS form submitted concurrently, to include a limitation, not to broaden the scope of the claim. Furthermore, it is believed that the Examiner initially conducted a search on subject matter directed to a method for the prophylaxis or treatment of a RSV or parainfluenza virus infection in a subject, comprising administering at least one pharmacological acceptable oligonucleotide of at least 10 nucleotides in length and wherein the antiviral activity of said oligonucleotide occurs principally by a non-sequence complementary mode of action. ***The initial search conducted was broader and would include oligonucleotides currently claimed.*** Thus, the Applicants are of the opinion that by restricting the subject matter claimed in claims 1, 2 and 14 to oligonucleotides having a sequence not comprising any CpG portion interacting with the immune system; or a sequence comprising only C, A or T nucleotides; or only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG, it should not require the Examiner to conduct an additional search in the art since the subject matter claimed in amended claims 1, 2 and 14 was already encompassed in the initial search conducted by the Examiner.

Further, the Krieg reference is only directed to a nucleic acid containing a specific nucleic acid sequence, namely a unmethylated cytosine-guanine dinucleotide (CpG) that activates the immune system via a sequence-dependent mechanism. Indeed, Krieg defines "immunostimulatory nucleic acid molecule" as:

"a nucleic acid molecule, which contains an unmethylated cytosine, guanine dinucleotide sequence (i.e. "CpG DNA" or DNA containing a cytosine followed by guanosine and linked by a phosphate bond) and stimulates (e.g. has a mitogenic effect on, or induces or increases cytokine expression by) a vertebrate lymphocyte" (Column 11, Lines 10-15).

In the specifications and the examples, Krieg et al. show that CpG containing oligonucleotides have immunostimulatory activity compared to non-CpG oligonucleotides (negative controls) having no or very low immunostimulatory activity (see for examples Fig. 1C, Fig. 2, Fig. 4B, Fig. 5, Fig. 7, Table 4, Table 8, Table 9, Column 19 lines 58-64, Column 21 lines 48-51, Column 22 lines 13-16, Column 24 lines 65-67, Column 25 lines 37-40,

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Column 27 lines 5-12, Column 28 lines 8-11, or Column 34 lines 36-40). In addition, Krieg et al. teaches the therapeutic uses of immunostimulatory nucleic acid molecules containing at least one unmethylated CpG dinucleotide (Column 33 line 11 to Column 35 line 20). Krieg et al. does not demonstrate, suggest or teach the activity or the use of non-CpG oligonucleotides for the treatment of viral infections.

Thus, in order to clearly distinguish the claims presently on file from the teaching found in Krieg et al., claim 1 has been amended in order to specifically encompass oligonucleotides having a sequence not comprising an immune system interacting CpG portion with the purpose of clearly distinguishing the subject matter recited in claim 1 from the teaching of Krieg et al.

In addition claim 2 has been amended to further define that the oligonucleotides comprises only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG which represent a selection of possible sequences disclosed in paragraph [0068] of the published application that do not have a CpG portion.

Finally, claim 14 has been amended in order to further define that the sequence of the oligonucleotides comprises only C, A or T nucleotides, which represents a selection of nucleotides disclosed in the publish specifications at paragraph [0068] that do not have a CpG portion.

Applicants submit that they are well aware that in order for an invention to be patentable, it must be new as defined in the patent law, which provides that an invention cannot be patented if: “(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent,” or “(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States...” It has never been the intent of the Applicants to claim more that they invented nor to claim subject matter that would not be new.

Thus, by specifying that the oligonucleotides have a sequence not comprising any CpG portion interacting with immune system; or a sequence comprising only C, A or T nucleotides; or only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG, applicants are claiming subject matter which is

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not only supported and/or deduced from the present application, but that is believed to be new and inventive.

It is believed that the 35 U.S.C. §102(b) rejection of the claims for allegedly being anticipated by Krieg et al. is improper, and withdrawal of this rejection is respectfully requested.

Therefore, the claims now on file are believed to be in condition for allowance. Reconsideration of the Examiner's rejections is respectfully requested.

Allowance of claims 1, 2, and 14 at an early date is solicited.

No additional fees are believed to be necessitated by this amendment. Should this be in error, authorization is hereby given to charge Deposit Account No. 19-5113 for any underpayment or to credit any overpayment.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application can be expedited.

Respectfully,

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Enc. -RCE form PTO/SB/30EFS
-RCE cover page
-Petition for extension of time